U.S. EPA Comments:

Technical Support Document: Derivation of Human Health Criteria and Risk Assessment Draft February 2014. Florida Dept. Environmental Protection (DEP)

February 5, 2015

Shrimp Apportionment and Depuration

- EPA previously made this comment and certain aspect were addressed ie., correcting of references. However, the overall comment is still unaddressed by FDEP and is of concern to EPA.
- EPA considers shrimp to be an estuarine species based on location during the majority of its
 development and lifespan. Because of this, harvest location is not relevant to the
 apportionment for the fish consumption rate.
- There is insufficient rationale for excluding BCF values less than 300 for shrimp caught offshore. The argument that lower BCF chemicals would be depurated in the marine environment makes an unsupported assumption that there would be zero residues of those chemicals. It also ignores shrimp life history where adults may have a significant residence time in estuarine waters. FDEP revised the text to include additional studies and study details to address this concern. However, the main study added (Parrish et al. 1973) is for a fish species (Spot) and is not applicable to shrimp species. Overall, the strength of the argument is still not convincing.
- The TSD also has several statements and assumptions regarding shrimp bioaccumulation that require reconsideration:
 - Cox and Anderson (1974) is only referenced for rapid depuration in large shrimp, whereas the report abstract shows rapid uptake of naphthalenes and slow depuration (25-33 days) in small shrimp. The text was revised to clarify the size of the large shrimp, but does not reference the rapid uptake and slow depuration in small shrimp.
 - Kobayaski et al. assumes that depuration will occur in clean water free from any pollutants. This assumption does not account for natural conditions. The text was not revised.
 - Several of the citations were either improperly cited or could not be readily accessed (e.g., Kobayashi et al., 1990).

Lipid Content Distribution

- Lipid content is tied to bioconcentration for specific trophic levels of fish species. The fish species utilized in the lipid distribution for Florida fish does not correlate with the species in the national data used for the FCR in this TSD. EPA feels that it is not accurate to assume that the lipid distribution is the same in these two cases. The lipid content distribution should not be tied to the overarching goal of the human health ambient water quality criteria that a state's residents should be able to consume their entire FCR from local waters, but to the FCR and BCFs utilized in developing the criteria themselves. The approach to determining lipid distributions has not been revised and still uses the FCRs from the Degner study which are specific to Florida. Thus it is still inconsistent with the FCRs (based on national data) that are used in FDEP's criteria calculations.
- EPA recommends that in a probabilistic simulation, the lipid content cannot be independent of the correlating individual fish species or trophic level summations.
- The recommended default lipid values described in the 2000 Methodology are based on national fish patterns of consumption and correlate with the use of a FCR based on national data. Due to the lack of sufficient data in the 2011 Exposure Factors Handbook on NHANES

data, the trophic levels for FCR are not able to be parsed apart. In this case EPA recommends using the default lipid value of 3% for trophic level 4 species.

Hazard Quotient and Criteria Derivation

- EPA finds merit in the idea of using an HQ as a risk management tool in order to assure
 protection of the 90th percentile of the population. EPA does not agree with the approach taken
 in the TSD which randomly assigns ranges for the criterion inputs for each pollutant criteria.
 This methodology truncates the population parameters and fails to account for the full range of
 population characteristics and exposure behaviors.
- This approach may be appropriate for site specific risk management decisions choosing the exposure input distributions pollutant by pollutant. However, the current revision activity targets revisions for the entire state, not on a waterbody by waterbody basis. EPA recommends that the approach follow the overall goal of the ambient water quality criteria, with uniform exposure assumptions for all contaminants. This requires using a single exposure distribution and critical exposure point for all contaminants. The approach as developed fails to provide the same level of protection for each chemical when the criteria inputs are varied among pollutants. If one pollutant attains an HQ of 1 using a truncated distribution of exposure inputs (i.e. fish consumption and water intake) and water bodies are protected using that distribution, then they would not necessarily protect the population against exposure to a second chemical that would need a broader range on exposure inputs to also attain an HQ of 1. Standard input distributions are needed for all pollutant criteria derivations in order to ensure consistent protection among pollutants in all waterbodies. The Feb 2014 version has been revised to include text that states the probabilistic risk analysis used uniform exposure distributions for all contaminants. (JAH Note)-I am unable to find the same revision that Gary found and don't believe that, even if present, it addresses the previously made comment and would recommend we reiterate this comment to FDEP.

RSC TSD

- EPA received and reviewed an additional TSD for proposed relative source contribution (RSC) terms for non-carcinogens. These RSCs are based on a State literature review and analysis and form the basis for alternative RSCs.
- EPA commends FDEP for attempting to address the RSC term on a State specific basis. To our knowledge, FDEP is the first State agency to attempt this process. EPA does, however, have the following concerns with the RSCs as presented.
- As far as the general development process:
 - FDEP indicated that they performed literature searches of more current literature to update information and fill gaps, however, it was not clear if this was done on just an as needed basis or whether it was done for all chemicals and all media. EPA recommends FDEP articulate its process for deciding which data sources and data to use for developing RSCs.
 - In addition to clarifying the process used to select data sources, EPA requests FDEP consider data from FDEP's drinking water program, air quality program and the FDA pesticide residue monitoring program in deriving appropriate RSCs.
 - As noted below, there are several instances where FDEP uses an inconsistent approach to selecting values for exposure concentrations from all media. A consistent approach/strategy should be used in selecting exposure concentrations for all media and all chemicals and that approach/strategy should be outlined within the TSD.

- The RSC equation on page 5 is incorrect because it uses an RfD for all exposure pathways including inhalation. Inhalation exposures should be compared to the chemical's RfC not the RfD; the equation needs to be revised accordingly.
- The approach to calculating the RSC puts the burden on the AWQC to be set low enough to avoid exceeding the RfD regardless of the magnitude of exposures from the other media. It assumes that the exposures from the other media will not or cannot be mitigated and only the ambient water concentration can be controlled to avoid exceeding the RfD. This is an important assumption for the public and others to understand and should be clearly stated in the methodology.
- Some of the key exposure assumptions are not consistent with what EPA is currently recommending for the 2014 Methodology. FDEP uses 2 L/day for the drinking water ingestion rate, whereas the 2014 Methodology is using 3 L/day. The use of this lower intake rate results in a lower estimated exposure from treated drinking water, which results in a higher RSC value. In addition, FDEP uses 70 kg for the adult body weight, whereas the 2014 Methodology is using 80 kg/day. The use of the lower body weight results in a lower RSC.
- o FDEP tends to use exposure assumptions that are based on mean values (such as the inhalation rate of 16 m³/day and food intake rate of 29 g/kg-day), whereas the 2014 AWQC Methodology is using the 90th percentile fish consumption rate. Thus there is a fundamental difference in the relative conservatism of the two exposure estimates (i.e., RSC calculation vs. AWQC calculation). The use of more conservative exposure assumptions in the RSC calculation would result in a lower RSC value. FDEP should fully explain why different assumptions are used in the development of the RSCs.

Chemical specific comments are as follows:

- The Methods section indicates that the most conservative estimate of exposure was used, but this does not seem to be the case for beryllium in treated drinking water. The "treated drinking water" analysis for beryllium cites several average concentrations for the U.S., but the lower average is selected for use in the calculation. More explanation is needed to explain why the lower value was selected and why that study was considered preferable over the other study. It was also unclear why U.S. concentrations were used rather than data specific to Florida. For the beryllium analysis, the most conservative mean soil and air concentrations were selected for the exposure calculations. However, the most conservative mean concentration was not selected for the treated drinking water exposure estimate. This inconsistency should be explained.
- on EPA's recommended limit due to taste considerations. In this case it would have been more appropriate to use the measured concentrations in drinking water that were presented in the text, rather than the recommended limit. Furthermore, the profile indicates that 2,4-dichlorophenol can occur in drinking water as a result of the chlorination process, thus it is likely that adequate monitoring data are available. The same approach was used for selecting the drinking water exposure concentration for chlorophenol and thus could be revisited.
- The nitrobenzene profile presents another example of inconsistency in the selection of exposure concentrations. FDEP presents a range of nitrobenzene sea water concentrations but then selected the maximum value for the exposure estimate. The use of the maximum value may be appropriate or may be overly conservative. If data are sufficient then it might be appropriate to use an upper bound on the mean (e.g., 95% UCL) or an upper percentile such as the 90th percentile, rather than the maximum.

- A consistent approach/strategy should be used in selecting exposure concentrations for all media and all chemicals.
- Table 2 in the Chloroform profile does not include the soil exposure pathway, and yet the profile indicates that soil can be contaminated with chloroform. Soil and the other primary exposure media should be evaluated for each chemical unless an explanation is provided as to why that media is excluded for a given chemical. In addition, "oceanic/marine concentrations" are discussed in some profiles and not others, again there needs to be consistency between the profiles or an explanation should be provided as to why a given media is being excluded for certain chemicals.
- o FDEP includes "Marine Fish" in the estimate of Dietary exposure; such as shown in the Dietary exposure summary tables for Chloroform and Methyl Bromide. On a related note, FDEP uses a selenium dietary intake value from the NHANES III study which appears to be based on total diet, and may be overestimating exposure since it does not specifically exclude fish and seafood from the total. Dietary sources comprise a significant portion of the total estimated selenium exposure and thus should be reviewed to determine whether the RSC needs revision.
- The diet items presented in Table 1 of the 1,2-dichlorobenzene profile are too limited and do not reflect a range of diet items, particularly fruits and vegetables. Furthermore the average dietary dose presented in the text below the table should be calculated from the weighted-average concentrations of all the food items based on the mass of each food consumed in the diet. The current approach may not be conservative if the more highly contaminated items represent a higher fraction of the diet.
- o FDEP assigned an RSC of 0.2 to five of the chemicals evaluated. This may be appropriate for four of the chemicals since they were lacking data for several or all exposure media. However, FDEP assigned an RSC of 0.2 to acrolein due to only a lack of dietary data. FDEP provides a number of food concentrations including upper end values that could be used in a conservative analysis of dietary exposures. We recommend reviewing the RSC for acrolein to ensure that it is not overly conservative.

Additional Comments

- The page numbers throughout the document need to be corrected/adjusted. The page numbers still need some adjustment Chapter 1 should start on page 1 and the appendices should have their own page numbering, such as A-1 for Appendix A.
- CAS Numbers should be listed with pollutants in all sections of the document. CAS numbers have been added to Table 3-4, but are not included in all sections such as Section 2.
- TSD PDF p. 61- Florida DEP is proposing rounding all draft criteria to 2 significant figures. EPA recommends following appropriate scientific rounding as described in section 2.7.3 in the 2000 Methodology. The heading of Table 3-1 still indicates that rounding was done to 2 significant figures. However, many criteria show more than 2 significant figures and it is not clear what approach was used.
- Appendix C in the TSD should list the source documents for the information presented.